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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,114	07/25/2003	Peter Paul Zilla	P-8794.05 Continuation 2	3869

7590 06/30/2008  
JAMES H. ACKLEY  
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EXAMINER
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WILLSE, DAVID H

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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06/30/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/627,114	<b>Applicant(s)</b> ZILLA ET AL.	
	<b>Examiner</b> Dave Willse	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 71-87 and 103-105 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 71-87 and 103-105 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 71, 72, 74, 77, 78, 84, and 103-105 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Starling et al., WO 98/43558 A1, which discloses a scaffold (page 13, lines 8-9; page 14, lines 14-17) containing interconnecting, uniformly shaped spherical pores occupied by an aggregate of bonded hollow microspheres (page 13, lines 4-8; page 14, lines 13-14; page 33, lines 24-28; etc.) comprising a concentration gradient of growth factors or other pharmaceutical agents (page 13, lines 15-17 and 23-24; page 33, lines 10-14 and 26-27), wherein the varying concentrations within the aggregate or ingrowth matrix (page 13, lines 26-31) are designed to perform the specific functions of driving the sustained diffusion and release of growth factors, anti-inflammatory agents, and/or anti-tumor agents (page 13, lines 11-13).

Concentration gradients are further enhanced as the outermost hollow microspheres are replaced by tissue ingrowth (page 13, lines 26-31).

Claims 71-87 and 103-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Starling et al., WO 98/43558 A1. Because the device can be used in the repair and augmentation of cartilage defects as well as bony defects (page 14, lines 6-8), an implant in the form of, for example, a bone screw having different pharmaceutical agent concentrations for localized treatment of soft and hard tissues would have been obvious from page 12, lines 3-4; page 13, lines 21-22; and so on in order to optimize tissue growth and integration. Regarding claim 73, hydrogels would have been obvious in order to provide greater control over the release of one or more of the substances. The further limitations of claims 75, 76, and 79-81 would have been obvious materials for facilitating tissue replacement of microsphere structure. Regarding claim 82, helically oriented channels are defined along the thread(s) of the aforementioned bone screw. Regarding claim 83, the particular range would have been obvious from the ranges specified at page 12, line 29, through page 13, line 3, and from the fact that smaller sizes can be used for soft tissue (page 14, lines 7-8). Regarding claims 85-87, the Starling et al. implant materials being incorporated into the sewing ring of a prosthetic heart valve, for example, would have been obvious to the ordinary practitioner in order to utilize the advantageous properties for tissue treatment and integration at the corresponding heart valve annulus.

The Applicant's remarks have been considered. The Applicant submits that the pores of Starling et al. are not interconnected (Applicant's reply of March 13, 2008: page 6, lines 10-11). Since coatings of collagen, protein, or the like (page 6, lines 31-33; page 16, lines 5-11) can be formed around *aggregates* of bonded hollow microspheres (page 14, lines 13-17), the pores

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contained by the coating and occupied by the aggregate are *necessarily* interconnected.

Moreover, the pores of the aggregates themselves are interconnected (page 13, lines 11-21). The Applicant may have misunderstood the grounds of rejection in suggesting that the growth factor is being interpreted as the claimed ingrowth matrix (Applicant's reply of March 13, 2008: page 6, lines 11-12). A comparison of instant claim 71 with the explanation in the paragraph bridging pages 2 and 3 of the Office action mailed on January 10, 2008, clearly shows that the claimed ingrowth matrix corresponds to the aggregate of bonded hollow microspheres in Starling et al. The reduced concentration within the open porosity through a microsphere wall, for example, provides the specific function of directing material or agent outwardly from the reservoir or cavity of said microsphere.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is 571-272-4762 and who is generally available Monday, Tuesday, and Thursday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

**/Dave Willse/  
Primary Examiner  
Art Unit 3738**